REMARKS

The following is in response to the Final Office Action dated December 28, 2009. Applicant has not amended any claims. Claims 1, 5–19, 23–38, and 42–56 remain pending.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1, 5–19, 23–38 and 42–56 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleged that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In support of the rejection, the Examiner alleged that the claim limitation of monitoring the therapy "while the output of the sensor was monitored," as required by the independent claims, is not supported by the originally filed application. The Examiner stated: "[a]lthough the portions of the disclosure cited by Applicant (e.g. par. 0035) appear to support defining an event (e.g., running) and monitoring therapy delivered by the device during the event and/or during the 'learning mode,' the Examiner was unable to find support for monitoring therapy while defining the event (i.e., monitoring the sensor)." The Examiner further stated: "[f]or instance, the patient could begin the 'event' (e.g., running) or initiate the learning mode; then the 'event' is defined based on monitoring the sensor; and *subsequently* the therapy is monitored by the device (as shown in Applicant's Figures 5 and 6)." The Examiner concluded that: "[t]hese figures lack, and the corresponding text is also deficient in describing, an embodiment wherein the 'initially defining' step occurs while 'monitoring therapy' (i.e., performed in parallel)."

Applicant respectfully traverses the rejection under 35 U.S.C. § 112, first paragraph. Applicant respectfully submits that the feature "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," recited in claim 1 and similar features in independent claims 19, 38, and 58 are described by Applicant's disclosure in such a way as to convey to one skilled in the art that Applicant possessed the claimed invention at the time of filing.

As noted above, the Examiner stated that paragraph **[0035]** of Applicant's disclosure supports defining an event and monitoring therapy delivered by the device during the event. However, the Examiner alleged that there is no recitation in the specification that supports

monitoring therapy while defining the event, and rejected the claims under 35 U.S.C. § 112, first paragraph on this basis.

Applicant notes that the written description requirement does not require exact recitation of the claim features in the specification. Rather the written description requirement requires that Applicant demonstrate that he or she possessed the claimed invention, which is demonstrated by the specification. To demonstrate that Applicant possessed the claimed invention, the specification need not provide exact recitation of the feature. The specification can demonstrate that Applicant possessed the invention through express, implicit, or inherent disclosure. For example, MPEP 2163(I)(B) states: "[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

Paragraph **[0062]** is one example location within Applicant's specification that provides express and implicit support for "monitoring therapy delivered by a medical device while the output of the sensor was monitored," as required by claim 1 and the similar features of claims 19, 38, and 58. Paragraph **[0062]**, which describes FIG. 6, states that "[p]rocessor 34 may record the sensor output or information over any length of time, may record multiple samples, and may make the recording or recordings at any time after entering the learning mode. Processor 34 may store the recording(s), or the result of an analysis, e.g. feature, Fourier, or wavelet, or the recording(s) in memory 36 as an event 52. Processor 34 records therapy information as a learned therapy 54 during operation in the learning mode (84), and associates the learned therapy 54 with the defined event 52 (86), as described above with reference to FIG. 5." (Emphasis added).

Paragraph **[0062]** makes clear that sensor output or information is recorded at any time and over any length of time after entering the learning mode. "Any length of time" necessarily includes the entire time, i.e., the entire duration of the learning mode. According to paragraph **[0062]**, monitoring of the delivered therapy also occurs during operation in the learning mode. Thus, paragraph [0062] supports examples in which the monitoring of the sensor output and the monitoring of the delivered therapy occur in parallel in the learning mode. In other words, if monitoring of the sensor output can occur any time and over any length time in the learning mode, and monitoring of the delivered therapy occurs in the learning mode, then, at least implicitly, paragraph **[0062]** supports monitoring therapy delivered by a medical device while the output of the sensor was monitored. Accordingly, paragraph **[0062]** demonstrates that

Applicant possessed the claimed feature of "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event," recited in claim 1 and similar features in independent claims 19, 38, and 58.

Applicant does not acquiesce that paragraph **[0062]** does not provide explicit support for the feature: "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event." Rather, Applicant respectfully submits that, at a minimum, paragraph **[0062]** provides implicit support for the feature and thereby demonstrates that Applicant possessed the claimed feature.

Furthermore, a determination of whether the specification meets the written description requirement is based on the knowledge of one of skill in the art. For example, MPEP 2163(II)(A)(2) states: "[t]he analysis of whether the specification complies with written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention." MPEP 2163(II)(A)(2) further states: "[s]uch a review is conducted from the standpoint of one of skill in the art at the time the application was filed."

Applicant respectfully submits that one of ordinary skill in the art, upon referencing paragraph **[0062]**, as well as, the entirety of the specification, would recognize that Applicant possessed the features of the claims.

As other examples, paragraph **[0035]** states "[p]atient 14 may...simply begin running and allow IMD 12 to record an exemplar of the sensor output while patient 14 is running...[w]hile patient 14 is running...patient 14 uses programming device 20, e.g., keypad 24, to change one or more stimulation parameters in an attempt to maintain adequate symptom control during the activity." Paragraph **[0059]** states "patient 14 adjusts stimulation parameters over a period of time after directing IMD 12 to enter the learning mode, e.g., during the event...so that IMD 12 learns appropriate adjustments to therapy to provide while patient 14 is running, and may adjust stimulation parameters while running to maintain effective and comfortable neurostimulation therapy."[1] Paragraph **[0066]** goes on to state "[f]or example, an event 52 may be patient 14 running, and the learned therapy 54 may include changes to stimulation parameters occurring at associated times during the "running" event such that effective and comfortable therapy is maintained."

[1] Emphasis added.

Initially defining the event comprises monitoring the sensor output for some period of time, and storing an indication of the monitored sensor output during that period of time as the defined event. It is clear from the cited paragraphs that the monitoring of the therapy may occur during the event, i.e., during the period of time in which the sensor output was monitored, so that an IMD or other device learns appropriate adjustments to therapy to provide during the event (when subsequently detected) to maintain effective and comfortable neurostimulation therapy.

Moreover, one of ordinary skill in the art would have read Applicant's specification to disclose that, in at least one example, monitoring therapy delivered by a medical device would occur while the output of the sensor was monitored to provide some possible, non-limiting advantages. For example, paragraph **[0011]** describes that a possible advantage is to provide a medical device that can "provide therapy that better addresses changes in the symptoms of a patient and/or level of efficacy or side effects of the therapy associated with an activity undertaken by the patient (emphasis added)." One of ordinary skill in the art would understand that monitoring for therapy changes during the definition of the event, rather than after the event had been defined and may have ended, would have facilitated addressing changes in symptoms during a subsequent occurrence the event.

In the Response to Arguments section, the Examiner seemed to allege that Applicant, in the previous response, confused the written description requirement and the enablement requirement. However, Applicant's previous remarks were not directed to the enablement requirement. Rather, Applicant's previous remarks rebutted the Examiner's allegation that the written description requirement is not met because the specification is limited to disclosing that the act of monitoring therapy and the act of monitoring the sensor output would only happen at different times. Applicant agrees with the Examiner that the enablement requirement is met.

Applicant respectfully disagrees with the Examiner that the specification only provides support for the act of monitoring therapy and the act of monitoring the sensor output happening at different times. In fact, for all the reasons described above, one of ordinary skill in the art would have read Applicant's disclosure in such a manner that the act of monitoring therapy and the act of monitoring the sensor output would have occurred at the same time, or at least overlapped in time.

For at least all the reasons advanced above, Applicant's disclosure conveys to one of ordinary skill in the art that the inventor(s) possessed the claimed invention at the time of filing.

Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for claims 1, 19, 38, and 56. The Examiner rejected the various dependent claims under 35 U.S.C. § 112, first paragraph due to their dependency upon claims 1, 19, and 38. Since the 35 U.S.C. § 112, first paragraph rejection is improper for claims 1, 19, and 38, the 35 U.S.C. § 112, first paragraph rejection for the various dependent claims is improper. Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 112, first paragraph for the various dependent claims.

Furthermore, Applicant draws the Examiner's attention to the requirements of MPEP 2163(III). MPEP 2163(III) requires the Examiner to evaluate the patentability of the claims on all statutory grounds even when rejecting the claims under 35 U.S.C. §112, first paragraph. Since the Examiner failed to reject the claims on any statutory grounds other than 35 U.S.C. §112, first paragraph, the Examiner seemed to recognize that the claims recite novel and non-obvious patentable subject matter. Accordingly, Applicant submits that the claims are in condition for immediate allowance and respectfully requests the Examiner to indicate as such.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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